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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,158	07/07/2003	**Jeffrey P. Gilbard**	2022(200696)	8240

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EXAMINER	
FAY, ZOHREH A	
ART UNIT	**PAPER NUMBER**
1627	

MAIL DATE	DELIVERY MODE
09/14/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/615,158	GILBARD, JEFFREY P.	
	Examiner	Art Unit	
	ZOHREH A. FAY	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-12 and 15-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-12 and 15-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/16/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 23, 2010 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 8-12 and 15-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueno (U.S. Patent 6,566,398) and Yano et al. and further over Troy et al. (U.S. 6,506,412) and Schneider et al. (US 6,353,022).

Ueno teaches the use of n-6 fatty acids containing oil and N-3 fatty acids containing oil such as DHA and EPA in a pharmaceutical formulation for the treatment of dry eye or dry mouth syndrome. See the abstract, column 4, lines 9-40. The addition of an antioxidant to such composition is taught in column 12, line 25. Yano et al. teach the addition of vitamin E to DHA can exert beneficial effects on organ dysfunction associated diseases. See the abstract. Troyer et al. teach the use of omega 3-fatty acids and omega 6-fatty acids in a pharmaceutical formulation for the treatment of dry eye syndrome. See the abstract and claims 1 and 17. Schneider et al. teach the use of Vitamin E as an antioxidant in combination with prostaglandins in an ophthalmic formulation for the treatment of dry eye.

The primary reference differs from the claimed invention in the use of the claimed fatty components in combination and the presence of vitamin E. It would have been obvious to a person skilled in the art to combine the claimed fatty components, considering that Ueno teaches the use of such compounds individually for the treatment of dry eye or dry mouth. The addition of antioxidants in general is also taught by Ueno.

Furthermore, Yano et al. teach the addition of vitamin E to DHA can be beneficial in treatment of many disorders.

One skilled in the art would have been motivated to combine the teachings of the above references, since Ueno and troy relate to the use of the claimed fatty components individually for the treatment of dry eye or dry mouth, the others relate to the use of vitamin E in combination with DHA as a beneficial factor for the treatment of disorders. Ueno also teaches the addition of antioxidants to the claimed fatty acids for the treatment of dry eye or mouth. To combine components being used individually for the treatment of dry eye or mouth, and use the combination for the same purpose would have been obvious to a person skilled in the art. See In re Kerkhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980). The determination of optimum proportions, amounts or the source of fatty components is considered to be within the skill of artisan in the absence of evidence to the contrary. Applicant's attention is drawn to In re Aller 105 USPQ 233 (C.C.P.A. 1955), which states " Normally, change in temperature, concentration, or both, is not patentable modification; however, such changes may impart patentability to process if ranges claimed produce new and unexpected result which is different in kind and not merely in degree from results of prior art; such ranges are termed "critical" ranges, and applicant has burden of proving such criticality; even though applicant's modification results in great improvement and utility over prior art, it may still not be patentable if modification was within capabilities of one skilled in art; more particularly, where general conditions of claim are disclosed in prior art, it is not inventive to discover optimum or workable ranges by routine experimentation".

Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 1-42 are properly rejected under 35 U.S.C. 103.

Applicant's arguments and remarks have been carefully considered, but are not deemed to be persuasive. Applicant in his remarks argues each reference individually and concludes that such reference does not teach the claimed combination. Applicant is reminded that the rejection is an obviousness rejection and not anticipation. The combination of the relied upon references clearly teach that omega-3 fatty acids and omega -6 fatty acids individually (Ueno et al.) or in combination (Troyer et al.) have been previously used for the treatment of dry eye syndrome. The above references also make clear that an anti-oxidant has been added to the combination of omega-3 fatty acid and omega-6 fatty acids. Schneider et al. teach vitamin E as an antioxidant added to fatty acids for the treatment of dry eye. Yano teaches that the addition of vitamin E to DHA can exert beneficial effect on TNF related diseases, which are associated with inflammation. Applicant's arguments regarding the higher amounts of claimed fatty acids have been noted, but are not deemed to be persuasive. Applicant's attention is directed to Troyer et al. (column 3, lines 55-56) reference which teaches 500 mg daily dose of omega-3 fatty acids. In claim 14, Troyer teaches the combination of fatty acids at 235 mg, which is within the scope of the claimed invention. Furthermore, the teachings of at least 94 mg for the combination of fatty acids reads on the concentrations of the claimed invention in the absence of setting forth any upper limits. Such language reads on any concentrations higher than 94 mg. Applicant in his

remarks also argues the use of the phrase "consisting essentially" in claims 33-36, and goes on by saying that such phrase excludes the presence of other components, such as vitamin A. Applicant is reminded that there is no evidence of record to show that Vitamin A would materially affect the nature of the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZOHREH A. FAY whose telephone number is (571)272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ZF

/Zohreh A Fay/
Primary Examiner, Art Unit 1627